

We Claim:

1. A pharmaceutical composition comprising:

- (a) an anticholinergic; and
- (b) a steroid,

optionally together with a pharmaceutically acceptable excipient,

the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

2. The pharmaceutical composition according to claim 1, wherein the anticholinergic is selected from the group consisting of: tiotropium salts, oxitropium salts, and ipratropium salts.

3. The pharmaceutical composition according to claim 2, wherein the anticholinergic is a salt with a counter-ion selected from chloride, bromide, iodide, *p*-toluene sulfonate, or methylsulfate.

4. The pharmaceutical composition of claim 3, wherein the counter-ion is bromide.

5. The pharmaceutical composition according to claim 1, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, rofleponide, GW 215864, KSR 592, ST-126, and dexamethasone.

6. The pharmaceutical composition according to claim 2, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, rofleponide, GW 215864, KSR 592, ST-126, and dexamethasone.

7. The pharmaceutical composition according to claim 3, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, rofleponide, GW 215864, KSR 592, ST-126, and dexamethasone.

8. The pharmaceutical composition according to claim 3, wherein the steroid is selected from the group consisting of: flunisolide, beclomethasone, triamcinolone, budesonide, fluticasone, mometasone, ciclesonide, and dexamethasone.

9. The pharmaceutical composition according to claim 1, wherein the weight ratios of the anticholinergic to the steroid are in the range of from 1:300 to 50:1.

10. The pharmaceutical composition according to claim 7, wherein the weight ratios of the tiotropium salt to the antihistamine are in the range of from 1:250 to 40:1.

11. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is in a form suitable for inhalation.

12. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is an inhalable powder, a propellant-containing metering aerosol, or a propellant-free inhalable solution or suspension.

13. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition further comprises a suitable physiologically acceptable excipient selected from the group consisting of: monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, and salts.

14. The pharmaceutical composition according to claim 2, wherein the pharmaceutical composition further comprises a suitable physiologically acceptable excipient selected from the group consisting of: monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, and salts.

15. The pharmaceutical composition of claim 11, wherein the excipient has a maximum average particle size of up to 250 μm .

16. The pharmaceutical composition of claim 12, wherein the excipient has a maximum average particle size of up to 250 μm .

17. The pharmaceutical composition of claim 13, wherein the excipient has a maximum average particle size of up to 250 μm .

18. The pharmaceutical composition of claim 14, wherein the excipient has a maximum average particle size of up to 250 μm .

19. The pharmaceutical composition of claim 15, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .

20. The pharmaceutical composition of claim 16, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .

21. The pharmaceutical composition of claim 17, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .

22. The pharmaceutical composition of claim 18, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .

23. A capsule containing a pharmaceutical composition according to claim 1 in the form of an inhalable powder.

24. A capsule containing a pharmaceutical composition according to claim 2 in the form of an inhalable powder.

25. A capsule containing a pharmaceutical composition according to claim 3 in the form of an inhalable powder.

26. A capsule containing a pharmaceutical composition according to claim 4 in the form of an inhalable powder.

27. A capsule containing a pharmaceutical composition according to claim 5 in the form of an inhalable powder.

28. A capsule containing a pharmaceutical composition according to claim 6 in the form of an inhalable powder.

29. A capsule containing a pharmaceutical composition according to claim 7 in the form of an inhalable powder.

30. A capsule containing a pharmaceutical composition according to claim 8 in the form of an inhalable powder.

31. A capsule containing a pharmaceutical composition according to claim 9 in the form of an inhalable powder.

32. A capsule containing a pharmaceutical composition according to claim 10 in the form of an inhalable powder.

33. A capsule containing a pharmaceutical composition according to claim 13 in the form of an inhalable powder.

34. A capsule containing a pharmaceutical composition according to claim 14 in the form of an inhalable powder.

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35. A capsule containing a pharmaceutical composition according to claim 15 in the form of an inhalable powder.

36. A capsule containing a pharmaceutical composition according to claim 16 in the form of an inhalable powder.

37. A capsule containing a pharmaceutical composition according to claim 17 in the form of an inhalable powder.

38. A capsule containing a pharmaceutical composition according to claim 18 in the form of an inhalable powder.

39. A pharmaceutical composition consisting essentially of:

- (a) an anticholinergic; and
- (b) a steroid,

wherein the pharmaceutical composition is in the form of an inhalable powder.

40. A pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is a propellant-containing inhalable aerosol and the anticholinergic and the steroid are in dissolved or dispersed form.

41. The pharmaceutical composition according to claim 40, wherein the propellant-containing inhalable aerosol comprises a propellant gas selected from hydrocarbons and halohydrocarbons.

42. The pharmaceutical composition according to claim 40, wherein the propellant-containing inhalable aerosol comprises a propellant gas selected from the group consisting of: *n*-propane; *n*-butane; isobutane; and chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane, and cyclobutane.

43. The pharmaceutical composition according to claim 41, wherein the propellant gas is TG134a, TG227, or a mixture thereof.

44. The pharmaceutical composition according to claim 40, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

45. The pharmaceutical composition according to claim 43, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

46. The pharmaceutical composition according to claim 44, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

47. The pharmaceutical composition according to claim 45, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

48. The pharmaceutical composition according to claim 40, wherein the amount of the anticholinergic or the steroid is up to 5 wt.% of the pharmaceutical composition.

49. A pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is propellant-free inhalable solution or suspension that further comprises a solvent selected from water, ethanol, or a mixture of water and ethanol.

50. The pharmaceutical composition according to claim 49, wherein the pH is between 2 and 7.

51. The pharmaceutical composition according to claim 50, wherein the pH is between 2 and 5.

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52. The pharmaceutical composition according to claim 49, wherein the pH of the pharmaceutical composition is adjusted by means of one or more acids selected from the group consisting of: hydrochloric acid, hydrobromic acid, nitric acid, sulfuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid, and propionic acid.

53. The pharmaceutical composition according to claim 49, further comprising other co-solvents or excipients.

54. The pharmaceutical composition according to claim 52, further comprising other co-solvents or excipients.

55. The pharmaceutical composition according to claim 53, wherein the co-solvent is selected from the group consisting of alcohols, glycols, polyoxyethylene alcohols, and polyoxyethylene fatty acid esters.

56. The pharmaceutical composition according to claim 53, wherein the co-solvent is selected from the group consisting of: isopropyl alcohol, propylene glycol, polyethylene glycol, polypropylene glycol, glycol ether, and glycerol.

57. The pharmaceutical composition according to claim 53, wherein the excipient is selected from the group consisting of: surfactants, stabilizers, complexing agents, antioxidants, preservatives, flavorings, pharmacologically acceptable salts, and vitamins.

58. The pharmaceutical composition according to claim 57, wherein the excipient is selected from the group consisting of: edetic acid, a salt of edetic acid, ascorbic acid, vitamin A, vitamin E, tocopherols, cetyl pyridinium chloride, benzalkonium chloride, benzoic acid, and benzoate salts.

59. A method of treating inflammatory or obstructive diseases of the respiratory tract in a patient in need of such treatment, the method comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition according to one of claims 1 to 12.

60. The method according to claim 59, wherein the pharmaceutical composition is administered to the patient by inhalation after nebulizing the pharmaceutical composition into an inhalable aerosol using an energy-operated free-standing or portable nebulizer that produces inhalable aerosols by means of ultrasound or compressed air.

61. A pharmaceutical composition consisting essentially of:

- (a) an anticholinergic;
- (b) a steroid;
- (c) a solvent;
- (d) benzalkonium chloride; and
- (e) sodium edetate.

62. A pharmaceutical composition consisting essentially of:

- (a) an anticholinergic;
- (b) a steroid;
- (c) a solvent; and
- (d) benzalkonium chloride.

63. A kit comprising one or more unit dosage containers containing a pharmaceutical composition, each unit dosage container containing a pharmaceutical composition comprising:

- (a) an anticholinergic; and
- (b) a steroid.

each optionally together with a pharmaceutically acceptable excipient,

the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

64. The kit according to claim 63, further comprising instructions with directions for using the kit.

65. A kit comprising:

- (a) a first container containing a first pharmaceutical formulation comprising an anticholinergic; and
- (b) a second container containing a second pharmaceutical formulation comprising a steroid,

each container each optionally further containing a pharmaceutically acceptable excipient, the anticholinergic and the steroid optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

66. The kit according to claim 65, further comprising instructions with directions for using the kit.